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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/237,183
Filing Date: January 26, 1999
Appellant(s): CHEIKH ET AL.

Gautam Prakash
Holly L. Prutz
David R. Marsh
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4 April 2007 appealing from the Office action mailed 7 November 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

1. *Ex parte Fisher* , 72 U.S.P.Q.2d 1020 (Bd. Pat. App. Int. 2004)
2. *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005)
3. US Patent Application 09/684,016
4. US Patent Application 10/361,942
5. US Patent Application 09/199,129
6. US Patent Application 09/920,953
7. US Patent Application 09/663,423

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 2 and 7-27 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

(a) The claimed nucleic acids are not supported by a specific asserted utility because the disclosed uses of these compositions are not specific and are generally applicable to any nucleic acid. The specification states that the nucleic acid compounds may be useful to obtain nucleic acid homologues, as nucleic acid markers and probes, in microarrays as gene-specific targets, to identify the presence of a polymorphism, to determine the level of expression of proteins, for

example. In fact, the specification summarized modern biotechnology generally but never connects **any** of the **specifically elected sequences** to any particular or specific utility. This wishlist desire for a utility for the claimed sequences falls short of a readily available utility.

Further, the claimed nucleic acids are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by applicant(s) to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or

protein compound(s) such that another non-asserted utility would be well established for the compounds.

(b) Claims 2 and 2-27 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility, or, alternatively, a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

(10) Response to Argument

A. Summary of Appellant's Position

The specification provides a specific, substantial, and well-established utility for the claimed nucleic acid sequences. Appellants have provided a statistically significant correlation between the claimed nucleic acid sequences and proteins from the sucrose pathway. The utility of proteins is well-established and the correlation between the claimed nucleic acid sequences and the proteins is specific. In setting forth reasonable correlations between the claimed nucleic acid sequences and the proteins, Appellants have demonstrated that the claimed invention has patentable utility. In other words, Appellants have satisfied the requirements of 35 U.S.C. §§ 101 and 112, first paragraph. (Brief page 4)

B. Appellant's Arguments

1. Firstly Appellant argues that the utilities of SEQ ID NOs: 11, 446, 935, 1108, 2042, 2166, 2252, 2644, 2681, and 2753 are specific because they are specific to SEQ ID NOs: 11, 446, 935, 1108, 2042, 2166, 2252, 2644, 2681, and 2753 and not "generally to any nucleic acid sequence". Appellant states that SEQ ID NO: 11 encodes a triose phosphate isomerase or

fragment thereof, SEQ ID, SEQ ID NO: 446 encodes a vacuolar H+ translocating-pyrophosphatase or fragment thereof, SEQ ID NO: 935 encodes a sucrose synthase or fragment thereof, SEQ ID NO: 1108 encodes a hexokinase or fragment thereof, SEQ ID NO: 2042 encodes a fructose 1,6-bisphosphate aldolase or fragment thereof, SEQ ID NO: 2166 encodes a fructose 6-phosphate 2-kinase or fragment thereof, SEQ ID NO: 2252 encodes an invertase or fragment thereof, SEQ ID NO: 2644 encodes a fructokinase or fragment thereof, SEQ ID NO: 2681 encodes an NDP-kinase or fragment thereof, and SEQ ID NO: 2753 encodes a UDP-glucose pyrophosphorylase or fragment thereof. Specification at page 24, lines 7 to 14 and Table A (pages 241 to 303). In other words, the specific utilities listed for the particular nucleic acid sequences are not shared by any general nucleic acid sequence.

2. Appellant argues that second, the utilities of SEQ ID NOs: 11,446, 935, 1108, 2042, 2166, 2252, 2644, 2681, and 2753 are substantial because the specification as filed provides well-defined and particular benefits, for each of these sequences including: as nucleic acid molecule markers and probes for each of these encoding sequences, Specification at page 71, line 8 to page 75, line 2; to identify and obtain nucleic acid homologues of these coding sequences, Specification at page 83, line 5 to page 84, line 15; in microarrays as gene-specific targets, Specification at page 104, line 3 to page 106, line 9; to identify the presence or absence of a polymorphism, Specification at page 85, line 20 to page 93, line 13; to determine the level or pattern of expression of proteins or mRNAs associated with one of these coding sequences, Specification at page 99, line 3 to page 103, line 18; and to overexpress or suppress one or more of these coding sequences in a transgenic plant, • Specification at page 129, line 9 to page 132, line 3.

3. Appellant argues that the utilities of SEQ ID NOs: 11,446, 935, 1108, 2042, 2166, 2252, 2644, 2681, and 2753 are well-established because the proteins encoded by these sequences are well-known. Triose phosphate isomerase, vacuolar H+ translocating-pyrophosphatase, sucrose synthase, hexokinase, fructose 1,6-bisphosphate aldolase, fructose 6-phosphate 2-kinase, invertase, fructokinase, NDP-kinase, and UDP-glucose pyrophosph0rylase are well known to one of ordinary skill in the art as proteins associated with the sucrose pathway in plants. See, e.g., Specification at pages 10 to 14. Moreover, the specification provides a statistically relevant correlation between the claimed nucleic acid sequences and the respective enzymes. Specifically, SEQ ID NO: 11 has an 80 percent identity with a triose phosphate isomerase, SEQ ID NO: 446 has an 80 percent identity with a vacuolar H+ translocating-pyrophosphatase, SEQ ID NO: 935 has an 80 percent identity with a sucrose synthase, SEQ ID NO: 1108 has an 84 percent identity with ahexokinase, SEQ ID NO: 2042 has an 80 percent identity with a fructose 1,6-bisphosphate aldolase, SEQ ID NO: 2166 has an 80 percent identity with a fructose 6-phosphate 2-kinase, SEQ ID NO: 2252 has an 80 percent identity with an invertase, SEQ ID NO: 2644 has an 80 percent identity with a fructokinase, SEQ ID NO: 2681 has a 79 percent identity with an NDP-kinase, and SEQ ID NO: 2753 has an 80 percent identity with a UDP-glucose pyrophosphorylase. Specification at pages 241 to 303 (Table A).

4. Finally, Appellant argues that the claimed nucleic acids satisfy 35 U.S.C. § 112. They state that the Examiner rejected claims 2 and 7 to 27 under 35 U.S.C. § 112, first paragraph, allegedly since the claimed invention is not supported by either a specific and/or substantial utility or a well-established utility, one of ordinary skill in the art "would not know how to use the invention." Final Action at page 5. Appellants submit that this rejection has been overcome

by the arguments set forth above with respect to the rejection under 35 U.S.C. § 101. In other words, Appellants respectfully submit that the claimed invention has specific, substantial, or well-established utility and request that the Board reverse the rejection of claims 2 and 7 to 27 under 35 U.S.C. § 112, first paragraph.

Response to Arguments

1. This is not persuasive, as stated previously. Absent factual evidence, one skilled in the art would have reason to doubt that sequence similarity alone would reasonably support the assertion that the biological activity of the claimed subject matter would be the same as that of the similar sequence. Furthermore, it is unclear whether the similar sequence identified in the prior art has actually been tested for the biological activity or whether this also is an asserted biological activity based upon sequence similarity to yet a different sequence. Note that it would have been well known in the art that sequence similarity does not reliably correlate to structural similarity and that structural similarity does not reliably result in similar or identical biological activities. For example, it would have been well known that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. In the absence of factual evidence characterizing the structural and functional components of the biomolecule, the effects of these changes are largely unpredictable as to which ones will have a significant effect and which ones will be silent mutations having no effect. Several publications document the unpredictability of the relationship between sequence, structure, and function, although it is acknowledged that certain specific sequences have been found to be conserved in biomolecules having related function following a significant amount of

further research. See Attwood (Science, 290:471-473, 2000); Gerhold et al. (BioEssays, 18(12):973-981, 1996); Wells et al. (Journal of Leukocyte Biology, 61(5):545-550, 1997); and Russell et al. (Journal of Molecular Biology, 244:332-350, 1994) (all cited previously). However, this level of factual evidence is absent here. (Re-iterated from the Non-final Office Action of 25 May 2006).

2. This is not persuasive. This is not persuasive, as the uses disclosed supports the requirement for further research in order to establish a patentable utility since such a use is clearly a research project without defining any specific or substantial utility for any of the list of proposed uses. Additionally, the specification lacks specific procedures for performing the use and thus also failing to provide a utility in currently available form. The claimed identifiable benefits, for example, use to encode triose phosphate, fructose 1,6-biphosphate aldolase, fructose 6-phosphate 2-kinase, invertase, frustokinase, NDP-kinase, or UDP-glucose pyrophosphorylase as nucleic acids markers and probes; to identify and obtain nucleic acid homologues; in microarray as gene specific targets; to identify the presence or absence of a polymorphism; use to transform plants; to determine the level or pattern of expression of a protein or mRNA associated with that nucleic acid molecule; and use to overexpress or suppress a desired protein do not have a specific asserted utility because the disclosed uses of these compositions are not specific to the claimed nucleic acids and are generally applicable to any nucleic acid. The research contemplated by applicant(s) to discover genes does not constitute a specific and substantial utility. Potential uses for nucleic acid homologue identification, for example, do not provide an immediate benefit. Similarly, the other listed and asserted utilities as summarized

above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of nucleic acids.

3. This is not persuasive. What is at issue is whether such a "utility" is a patentable utility that meets the criteria of 35 U.S.C. § 101. Appellants assert that the utility of the above cited sequences should be considered to be well-established because the proteins encoded by the sequences are a well-known proteins. While it is true that triose phosphate isomerases, sucrose synthases, etc. are know proteins, the instant specification fails to provide any evidence that the recited sequences are in fact such, other than to provide BLAST search alignment identity scores. As was recited above it would have been well known in the art that sequence similarity does not reliably correlate to structural similarity and that structural similarity does not reliably result in similar or identical biological activities.

4. This is not persuasive. Contrary, to Appellant's assertions, Appellants have not disclosed how to use the claimed nucleic acids according to the present invention. The specification as filed describes 2,814 distinct nucleic acid molecules, however there is no specific guidelines provided in the specification as filed that would teach the skilled artisan how to use the full scope of the claimed invention without undue experimentation.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Art Unti 1631

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